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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

BARTON, JEFFREY THOMAS

ART UNIT PAPER NUMBER

1753

DATE MAILED: 08/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/907,001

Applicant(s)

YAGER ET AL

Examiner

Jeffrey T. Barton

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 June 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-26, 28-31 and 34-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24-26, 31 and 34-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

1. The amendment filed on 2 June 2005 does not place the application in condition for allowance.

Status of Objections and Rejections Pending Since the

Office Action of 27 October 2004

2. The objection to the specification is withdrawn due to Applicants' amendment.
3. The objection to Claim 24 is withdrawn due to Applicants' amendment.
4. All rejections made in the prior action are withdrawn due to Applicants' amendment.

Claim Objections

5. Claims 35 and 37 are objected to because of the following informalities: the term "self-assembly dendrimers" is awkward. The originally recited "self-assembling dendrimers" would be clearer and more in line with the language used in the art. Appropriate correction is required.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 24, 25, and 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Soane et al in view of either Ekström et al or Kaltenbach et al.

Addressing claim 24:

Soane et al disclose a method of manufacturing a microelectrophoresis chip comprising: lithographically forming the channel of the device (Column 5, lines 36-39), and forming a plurality of electrodes within the channel (Column 4, line 63 - Column 5, line 11) wherein the electrodes are disposed in the central region of the channel. (Figure 1, Column 4, lines 64-65; In order for only 7 electrodes to be present along the channel of Figure 1, the pairs 5-5', 6-6', etc. must be joined as single electrodes. This would require electrode portions to cross the channel, and thus be disposed in a central region of the channel, between two edges. The embodiment described at Column 7, lines 27-34 also reads on the claim.)

Addressing claim 29:

In addition to the disclosure cited above for claim 24, Soane et al disclose the disposition of electrodes to generate fields in at least two non-parallel directions within a plane parallel to the major surface of the substrate. (Column 7, lines 18-24; also Column 8, lines 11-20 - the fields in branch channels will not be parallel to those in the main channel)

Soane et al do not explicitly disclose lithographically forming the channel according to steps a-c of claims 24 and 29.

Ekström et al disclose a method of preparing a microfluidic chip comprising the steps of: lithographically forming a mold that is a reverse of the desired channel structures (Column 4, line 61 - Column 5, line 30); casting or imprinting the channels in

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a polymeric substrate as a negative impression of the mold (Column 5, lines 31-57); and fusing the polymeric substrate to a solid support (Column 6, lines 38-55)

Kaltenbach et al disclose a method of preparing a microfluidic chip comprising the steps of: lithographically forming a mold that is a reverse of the desired channel structures (Column 7, line 55 - Column 8, line 30); casting the channels in a polymeric substrate as a negative impression of the mold (Column 8, lines 16-30); and fusing the polymeric substrate to a solid support (Column 10, lines 49-55)

It would also have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Soane by preparing the mold and forming the substrate according to steps a-c, as taught by either Ekström et al or Kaltenbach et al, because Soane et al state that conventional lithographic techniques can be used to produce their device (Column 5, lines 36-39), and the devices produced by Ekström et al and Kaltenbach et al are similar in structure and function to those of Soane et al.

Addressing claims 25, 28, and 30:

Regarding claims 25 and 30, Soane et al disclose the channel being 5-25 microns in depth. (Column 4, lines 43-47)

Regarding claim 28, Soane et al disclose the disposition of electrodes to generate fields in at least two non-parallel directions. (Column 7, lines 18-24; also Column 8, lines 11-20 - the fields in branch channels will not be parallel to those in the main channel)

10. Claims 26 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Soane et al and either Ekström et al or Kaltenbach et al as applied to claim 24 above, and further in view of Sethi et al.

Soane et al and either Ekström et al or Kaltenbach et al disclose methods as described above. In addition, Soane et al suggest plural elements being encompassed by their disclosure. (Column 4, lines 20-23)

None among Soane et al, Ekström et al, and Kaltenbach et al explicitly disclose the preparation of plural separation channels in a substrate.

Sethi et al disclose lithographic preparation of several separation channels in a single substrate. (Figure 11)

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the combined methods of Soane et al, Jinno et al, Ross et al, and either Ekström et al or Kaltenbach et al by fabricating plural separation channels on the substrate, as taught by Sethi et al, because Soane et al suggest such multiple features and it would allow parallel separations in a single device, with obvious advantages in analysis throughput.

11. Claims 34 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Soane et al and either Ekström et al or Kaltenbach et al as applied to claims 24 and 29 above, and further in view of Jinno et al and Ross et al.

Soane et al and either Ekström et al or Kaltenbach et al disclose a combined method as described above in addressing claims 24 and 29. Soane et al also disclose use of conventional separation media in their channel. (Column 4, lines 52-55)

None among Soane et al, Ekström et al, and Kaltenbach et al explicitly disclose using a separation medium comprising water-soluble fullerenes.

Jinno et al disclose the use of buckminsterfullerene (C_{60}) as a chromatographic stationary phase having unique selectivity for the analyzed compounds. (Abstract, Introduction section)

Ross et al disclose that fullerenes of the formula C_n have a degree of water-solubility. (Abstract)

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Soane by replacing the separation medium with a medium comprising fullerenes, as taught by Jinno et al, because Jinno et al teach that they have unique selectivity that would be useful in certain separations, and Soane et al suggest a wide range of media suitable for use in their device (Column 4, lines 52-55). Ross et al teach that fullerenes such as those disclosed by Jinno et al have some solubility in water, which therefore meets the claim limitations.

12. Claims 35 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Soane et al and either Ekström et al or Kaltenbach et al as applied to claims 24 and 29 above, and further in view of Tanaka et al and Newkome et al.

Soane et al and either Ekström et al or Kaltenbach et al disclose a combined method as described above in addressing claims 24 and 29. Soane et al also disclose use of conventional separation media in their channel. (Column 4, lines 52-55)

None among Soane et al, Ekström et al, and Kaltenbach et al explicitly disclose using a separation medium comprising self-assembling dendrimers.

Tanaka et al disclose using dendrimers as carriers in an electrophoretic separation, in which the separation was influenced by differential binding of the analytes to the dendrimers and dendrimer size. (Abstract, Figures 1 and 2) The size and binding effects show the dendrimers acting as obstacles to analyte migration.

Newkome et al disclose the preparation of self-assembling dendrimers. (Abstract, Experimental section)

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Soane by replacing the separation medium with a medium comprising dendrimers, as taught by Tanaka et al, because Tanaka et al teach that dendrimers work well as an alternative to surfactants and their use results in different selectivity that would be useful in certain separations (Page 959-960), and Soane et al suggest a wide range of media suitable for use in their device (Column 4, lines 52-55). Additionally, it would have been obvious to use self-assembling dendrimers, the preparation of which was taught by Newkome et al, because it would simplify dendrimer synthesis, and they would be reasonably expected to provide similar benefits to those disclosed by Tanaka et al.

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13. Claims 24-26 and 28-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clark et al in view of either Ekström et al or Kaltenbach et al.

Addressing claim 24:

Clark et al disclose a method of manufacturing a microelectrophoresis chip comprising: lithographically forming the channel of the device (Column 2, lines 25-31), and forming a plurality of electrodes within the channel (Figure 1; Column 2, lines 36-47) wherein the electrodes are disposed in the central region of the channel. (Figure 2; Electrodes are disposed along the height of the sidewall in Figure 2, therefore, they are disposed between the top and bottom edges of the channel.)

Addressing claim 29:

In addition to the disclosure cited above for claim 24, Clark et al disclose the disposition of electrodes to generate fields in at least two non-parallel directions within a plane parallel to the major surface of the substrate. (Hundreds of different non-parallel electric fields could be applied using the electrodes shown in Figures 1 and 2)

Clark et al do not explicitly disclose lithographically forming the channel according to steps a-c of claims 24 and 29.

Ekström et al disclose a method of preparing a microfluidic chip comprising the steps of: lithographically forming a mold that is a reverse of the desired channel

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structures (Column 4, line 61 - Column 5, line 30); casting or imprinting the channels in a polymeric substrate as a negative impression of the mold (Column 5, lines 31-57); and fusing the polymeric substrate to a solid support (Column 6, lines 38-55)

Kaltenbach et al disclose a method of preparing a microfluidic chip comprising the steps of: lithographically forming a mold that is a reverse of the desired channel structures (Column 7, line 55 - Column 8, line 30); casting the channels in a polymeric substrate as a negative impression of the mold (Column 8, lines 16-30); and fusing the polymeric substrate to a solid support (Column 10, lines 49-55)

It would also have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Clark et al by preparing the mold and forming the substrate according to steps a-c, as taught by either Ekström et al or Kaltenbach et al, because Clark et al state that conventional lithographic techniques can be used to produce their device (Column 2, lines 25-31), and the devices produced by Ekström et al and Kaltenbach et al are similar in structure and function to those of Clark et al.

Addressing claims 25, 26, 28, 30, and 31:

Regarding claims 25 and 30, Clark et al disclose channel depths of 50 microns. (Column 2, lines 33-35) However, in *Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), *cert. denied*, 469 U.S. 830, 225 USPQ 232 (1984), the Federal Circuit held that, where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the

claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device. No change in operability of the device of Clark et al would result from using somewhat shallower channels.

Regarding claims 26 and 31, Clark et al disclose plural channels in a chip.

(Figure 5)

Regarding claim 28, Clark et al disclose the disposition of electrodes to generate fields in at least two non-parallel directions. (Column 7, lines 18-24; also Column 8, lines 11-20 - the fields in branch channels will not be parallel to those in the main channel)

14. Claims 34 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clark et al in view of either Ekström et al or Kaltenbach et al as applied to claims 24 and 29 above, and further in view of Jinno et al and Ross et al.

The reasoning for this rejection parallels that given in paragraph 11 above. Like Soane et al, Clark et al disclose disposition of a broad range of separation media in their channels. (Column 3, line 37 - Column 5, line 10)

15. Claims 35 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clark et al in view of either Ekström et al or Kaltenbach et al as applied to claims 24 and 29 above, and further in view of Tanaka et al and Newkome et al.

The reasoning for this rejection parallels that given in paragraph 12 above. Like Soane et al, Clark et al disclose disposition of a broad range of separation media in their channels. (Column 3, line 37 - Column 5, line 10)

Response to Arguments

16. Applicant's arguments filed on 2 June 2005 have been fully considered but they are not persuasive.

Contrary to Applicants' arguments, Soane et al do teach electrodes disposed within a separation channel, as described above. Clark et al also disclose a device that meets this new limitation, as described above.

Applicants also argue that the cited Jinno et al and Ross et al references do not meet the limitation to a medium comprising water-soluble fullerenes. Ross et al show that fullerenes possess a degree of water solubility, which they disclose in the final sentences of their abstract. Any degree of water solubility would meet this limitation, and all fullerenes are soluble in water to a certain (albeit typically small) extent. The fullerenes used by Jinno et al would meet the limitations presented in claims 34 and 36, but Ross et al provide an additional, more explicit disclosure.

For at least the above reasons, Applicants' arguments are not persuasive.

Conclusion

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Jeffrey Barton, whose telephone number is (571) 272-1307. The examiner can normally be reached Monday-Friday from 8:30 am – 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen, can be reached at (571) 272-1342. The fax number for the organization where this application or proceeding is assigned is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

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For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197 (toll-free).

JTB
July 29, 2005



ALAN DIAMOND
PRIMARY EXAMINER

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